RECEIVED AT DRUG SAFETY SURVEILLANCE
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McNEIL CI
FOR:

Individual Safety Report

3037716-8-00

FDA on 11/16/E

Page ____ of ____

FDA use on

A. Patient information

1. Patient identifier	2. Age at time of event:	3. Sex	4. Weight
Case # 8 In confidence	30 yrs or ____ Date of birth:	(X)female ( )male	lbs or 75 kgs

B. Adverse event or product problem

1. X Adverse event and/or Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)

- (X) death 2/16/94 (mo/day/yr)
- ( ) life-threatening
- (X) hospitalization - initial or prolonged
- ( ) disability
- ( ) congenital anomaly
- ( ) required intervention to prevent permanent impairment/damage
- ( ) other:

3. Date of event	4. Date of this report
2/10/94 (mo/day/yr)	02/12/98 (mo/day/yr)

5. Describe event or problem

Reports of 19 cases complied by attorney & sent to FDA;Agency forwarded these reports to McNeil upon request to Docket No.77N-094W,Ref.94,Vol.6 of 7. Of the 19 cases,11 were previously submitted by McNeil(MFR# 0158783A, 0171537A,0284020A, 0325998A, 0374114A, 0495613A, 0505064A, 0505223A, 0505252A, 0599479A,0673820A). Case #8 indicates 30 yoF w/hx of heavy alcohol use took 50-60 Extra Strength TYLENOL Tablets over 5-6 days for flu-syndrome w/heavy alcohol every day. A few days later,on 2/10/94 pt admitted to hosp w/ABDOMINAL PAIN, vomiting & THROMBOCYTOPENIA. Pt transferred (2/13/94) to 2nd hosp w/acute liver failure, coagulopathy(COAGULATION DISORDER),thrombocytopenia. Developed increasing ICP w/focal seizures,HEPATORENAL SYNDROME,hepatic encephalopathy & cerebellar edema(ACUTE BRAIN SYNDROME). Pt expired(2/16/94). Autopsy report indicates massive coagulative necrosis of the liver, which is cause of DEATH; necrosis is so extensive that exact etiology cannot be determined.Discharge dx listed as: Pulmonary HEPATIC FAILURE; hx of EtOH abuse; Tylenol OVERDOSE.

6. Relevant tests/laboratory data, including dates

On 2/11/94 SGOT=876, SGPT= 328, Bili=1.4, PT=16; on 2/13/94 acetaminophen level=4.1 mcg/ml, T bili=4.1, SGOT=24685, SGPT=6895, alk phos=318, PT=16, WBC=6.7 w/shift to left, plt=7000, BUN/CR=13/0.6; (See Sect.B.7.)

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

multiple admissions for chronic and acute alcohol abuse, chronic disease from alcohol abuse, gastritis, bulimia, drug abuse (cocaine and marijuana)

(Sect. B.6. cont): 2nd hospital: on unspecified date,Bili=5, SGOT=9588, SGPT=3899, alk phos=317, PT=453, BUN/CR=20/3.3, urine positive for opiates (See Sect.C.10)

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)

#1 Extra Strength TYLENOL Tablets

#2

2. Dose, frequency & route used	3. Therapy dates (if unknown, give duration) from/to (or best estimate)
#1 25-30 grams, po	#1 2/94; over 5-6 days
#2	#2

4. Diagnosis for use (indication)

#1 flu-syndrome

#2

5. Event abated after use stopped or dose reduced

#1 ( ) Yes ( ) No (X) N/

#2 ( ) Yes ( ) No ( ) N/

6. Lot # (if known)	7. Exp. date (if known)
#1 Unknown	#1 Unknown
#2	#2

8. Event reappeared after reintroduction

#1 ( ) Yes ( ) No (X) N/

#2 ( ) Yes ( ) No ( ) N/

9. NDC # - for product problems only (if known)

- -

10. Concomitant medical products and therapy dates (exclude treatment of event)

none (Cont'Sect.B.7) autopsy report: urine toxicology screen positive for opiates, but all other substances, including cocaine were negative

G. All manufacturers

1. Contact office - name/address (& mfr/labeler site for devices)

McNeil Consumer Products Company
Medical Affairs
7050 Camp Hill Road
Ft. Washington, PA 19034

2. Phone number: 215-233-7820

3. Report source (check all that apply)

- ( ) foreign
- ( ) study
- (X) literature
- ( ) consumer
- (X) health professional
- ( ) user facility
- ( ) company representative
- ( ) distributor
- ( ) other: attorney

4. Date received by manufacturer (mo/day/yr): 12/31/97

5.
- (A) NDA # 17-552
- IND #
- PLA #
- pre-1938 ( ) Yes
- OTC product (X) Yes

8. If IND, protocol #

7. Type of report (check all that apply)

- ( ) 5-day (X) 15-day
- ( ) 10-day ( ) periodic
- (X) Initial ( ) follow-up #

9. Mfr. report number: 0932383A

8. Adverse event term(s)

PAIN ABDOMINAL
THROMBOCYTOPENI
COAGULATION DIS
HEPATORENAL SYN
BRAIN SYND ACUT
DEATH
LIVER FAILURE
OVERDOSE

E. Initial reporter

1. Name, address & phone #

[redacted]

2. Health professional?	3. Occupation	4. Initial reporter also sent report to FDA
( ) Yes (X) No	attorney	( ) Yes ( ) No (X) Unk

FDA Facsimile Form 3500A

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.